

REMARKS

Reconsideration of the present application is respectfully requested.

Applicants thank the Examiner for the courtesy of the interview held on February 7, 2008. The above amendments and following remarks are responsive to the interview and reflect the points discussed at the interview.

**I. Disposition of the claims**

Claims 9, 16, 18, 24, and 31-36 are pending.

Claims 9, 16, 18, and 24 are rejected.

Claims 31-36 are new and support for the new claims is believed obvious from antecedent basis in the claims on which the new claims depend. No new matter is added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate status identifier.

**II. Obviousness rejections**

Each of the two obviousness rejections will be handled under separate headers in reverse order compared with the order in which the rejections appear in the Office action.

**A. *Meguro et al. (4,687,777)***

Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meguro et al. (4,687,777). Office action, p. 5. According to the record, Meguro et al. teach antidiabetic agents including pioglitazone. Office action, p. 5. The rejection reasons that “one skilled in the art would have been motivated to improve or treat acidosis since acidosis is considered to be one complication associated with diabetes....” Office action, p. 5.

Even if “one skilled in the art would have been motivated to improve or treat acidosis,” that fact would not allow one to conclude that he/she should use pioglitazone for that purpose. The Examiner himself stated that Meguro et al. “does not teach the pioglitazone is used to improve and treat acidosis.” Office action, p. 3. In fact, the entire body of evidence of record fails to establish that, at the time of the present invention, one of ordinary skill in the art would have recognized pioglitazone’s use for improving or treating acidosis. As such, before the time of the present invention, there was no reason to use pioglitazone for improving or treating acidosis.

And this position is consistent with the Examiner’s findings in the second Office action on the merits. Office action of 04-21-2005, pp. 2-4. The previous versions of the rejected claims were rejected as nonenabled, “because the specification, while being enabling for treating acidosis with pioglitazone hydrochloride, does not reasonably provide enablement for other insulin sensitizers ....” Office action of 04-21-2005, p. 2. (The specification contains data for pioglitazone. See Exs. 1-3.) In the rejection, under the heading, “The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art,” Office action of 04-21-2005, p. 3 (emphasis in the original), the Examiner stated that “[t]he present invention is unpredictable unless experimentation is shown for the other insulin sensitizers ....” In other words, the Examiner clearly found that one of ordinary skill in the art would not have recognized that pioglitazone could have been used for improving or treating acidosis in the absence of experimental data, because such results would have been unpredictable.

In short, based on the Examiner’s own findings of record, using pioglitazone for improving or treating acidosis would have led to unpredictable results. Thus, the rejection should be withdrawn.

***B. Meguro et al. (4,687,777) in [view off] Windholz et al.***

Claims 16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meguro et al. (4,687,777) in view of Windholz et al. (Merck Index). As in the previous rejection, Meguro et al. teach antidiabetic agents including pioglitazone. Office action, p. 3.

Although presently articulated as follows: “Windholz et al... disclose insulin as a well-known compound used to treat diabetes and complications associated with diabetes,” Office action, p. 3. It is believed that Windholz et al. was cited to show that insulin is an antidiabetic. *Cf.* Amendment dated 12-14-2004, p. 14. The rejection reasons that “one skilled in the art would have been motivated to improve or treat acidosis since acidosis is considered to be one complication associated with diabetes in the absence of evidence to the contrary,” Office action, p. 3, and that “the combination ... into a single composition would give an additive effect in the absence of evidence to the contrary.” Office action, p. 4.

Even if “one skilled in the art would have been motivated to improve or treat acidosis since acidosis ...” that fact would not allow one to conclude that he/she should use pioglitazone, alone or in combination, for that purpose. As noted above, based on the Examiner’s own findings of record, using pioglitazone, alone or in combination, for improving or treating acidosis would have led to unpredictable results.

And even if one of ordinary skill in the art could have combined pioglitazone and insulin, there is no evidence of record to suggest that before the time of the present invention one of ordinary skill in the art would have recognized that the results of the combination were predictable. Thus, the rejection should be withdrawn.

### **III. The new claims**

The new claims 31-36 are believed patentable for the same reasons as articulated above with respect to the base claims on which each new claim depends. Support for new claims 35-36 regarding “type II diabetes” can be found in Paragraph 0181 of the specification. Therefore, there is no new matter added.

### **Conclusion**

It is believed that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

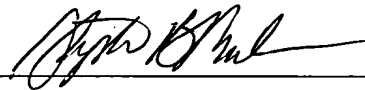
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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